

JAN 12 2001

K003253

SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR: Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581 -0587

CONTACT PERSON: Sara A. Bailey

DEVICE NAME: Constrained Elbow

PRODUCT CODE: JDC (888.3150)

PRODUCT CLASSIFICATION: Class II

INDICATIONS FOR USE:

The Constrained Elbow is indicated for use with the following conditions:

- Non-Inflammatory Degenerative Joint Disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Revisions where other treatments or devices have failed
- Correction of severe functional deformity
- Treatment of acute or chronic fractures with humeral epicondyle involvement which are unmanageable using other treatment methods

This device is intended to be used with bone cement.

DEVICE DESCRIPTION:

The Constrained Elbow is a total elbow prosthesis comprised of an ulnar and humeral component. Placing the humeral articulation through the ulnar articulation links the ulnar and humeral components. The humeral articulation is attached to the humeral stem with two screws. The screws pass through the humeral articulation, through a portion of the humeral stem, and back into the humeral articulation on both sides of the ulnar component. The pins are placed in a posterior position that is not parallel to the axis of rotation. The humeral components are available with or without an anterior flange. All humeral and ulnar components are manufactured with or without bond coat. Bond coat is a thin layer of porous coating.

The device design allows the load to be carried at the primary articulation. The primary articulation is the spherical interface between the humeral condyles and the ulnar bearing. The secondary articulation is the axle attached to one condyle, that fits into the hole of the opposite condyle. This articulation was aimed to prevent dislocation of the joint in extreme situations where a tensile load

may occur. The geometry of the components are designed to minimize bone loss and eliminate sharp resection cuts.

The humeral stem has been designed to incorporate an eight degree carrying angle with a five degree internal rotation to closely match the anatomical morphology. The ulnar component incorporates a bound stem and neck angle also designed to closely match the anatomical morphology.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

- 1) Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.
- 2) Early or late postoperative infection and allergic reaction.
- 3) Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
- 4) Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
- 5) Periarticular calcification or ossification, with or without impediment of joint mobility.
- 6) Inadequate range of motion due to improper selection or positioning of components.
- 7) Undesirable shortening of limb.
- 8) Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
- 9) Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
- 10) Fretting and crevice corrosion can occur at interfaces between components.
- 11) Wear and/or deformation of articulating surfaces.
- 12) Postoperative bone fracture and pain.

SUBSTANTIAL EQUIVALENCE: The Constrained Elbow is similar to Zimmer's Coonrad/Morrey Total Elbow (K001989), Biomet's Biaxial™ Total Elbow (K980428), Biomet's ABC Total Elbow (K972691), and Osteonic's Solar™ Total Elbow (K980502).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 12 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sara A. Bailey
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K003253
Trade Name: Constrained Elbow
Regulatory Class: II
Product Codes: JDC
Dated: October 13, 2000
Received: October 17, 2000

Dear Ms. Bailey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Miriam C. Provost
for

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K003253

DEVICE NAME: Constrained Elbow

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(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K003253